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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,122	11/12/2003	Jurgen Brinkhues	9003-286US	6214
<div>570 7590 08/02/2007 AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103</div>				
			EXAMINER MEHTA, BHISMA	
			ART UNIT .3767	PAPER NUMBER
			MAIL DATE 08/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,122	Applicant(s) BRINKHUES, JURGEN	
	Examiner Bhisma Mehta	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 16 is objected to because of the following informalities: Claim 16 recites the limitations "the outer circumferential edge of the inert film" in lines 2-3 and "the outer circumferential edge" in line 4. There is insufficient antecedent basis for these limitations in the claim. It should also be made clear which circumferential edge, i.e., the circumferential edge of the continuous sealing zone or the circumferential edge of the inert film, is being referred to by the use of "the outer circumferential edge" in line 4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear which outer circumferential edge is being referred to in line 4. In the case that it is the outer or outermost circumferential edge of the inert film, it is unclear how the sealing zone can slightly project beyond the circumferential edge of the inert film when it has already been established that the sealing zone forms a plane with the entire outer or outermost circumferential edge of the inert film.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawlikowski (U.S. Patent No. 4,929,231) in view of Pharma Gummi Wimmer West GmbH (EP 0 148 426) ("Pharma Gummi"). In Figure 1, Pawlikowski shows a piston stopper comprising a base body (28) with a displacement transferring element (24) and a piston section (34). The piston section in a working position faces the contents of a syringe or carpule cylinder (10). The outer circumference of the piston section (34) abuts against the syringe or carpule cylinder (10). The piston stopper has an uncoated sealing section adjacent to the piston section (34) and which abuts flat against the syringe or carpule cylinder (34). At least one continuous sealing lip (at 28 in Figure 1) is provided on the outer circumference of the sealing section. On an outer circumference of the sealing section, there is an annular continuous sealing zone. An outermost circumferential edge of the continuous sealing zone forms a plane with, is directly adjacent to and is in continuous abutting contact with an entire outermost circumferential edge of the piston section (34). At least a portion of the sealing zone is provided as a straight extension to the outer or outermost circumferential edge of the piston section (34). Pawlikowski discloses the piston stopper substantially as claimed. Even though Pawlikowski discloses a portion of the base body being made from an

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elastomer (lines 35-40 of column 2), Pawlikowski is silent on the base body (28) being made substantially from an elastomer and being made in one piece. Also, even though Pawlikowski discloses that the displacement transferring section is integral with the base body, Pawlikowski is silent on the specifics of the base body (28) comprising a receiving cavity. Pawlikowski is also silent on the piston section (34) being enclosed in a cap-shaped inert film and where the film comprises a fluorinated polymer film. In Figure 18, Pharma Gummi shows a rubber piston stopper (33) having multiple sealing lips (34, 35, 36) and a receiving cavity where a cross-section of the receiving cavity tapers out toward an opening of the receiving cavity. In lines 1-10 of page 2, Pharma Gummi discloses the piston stopper as being made essentially or substantially from an elastomer such as rubber. As shown in Figure 18, the base body of the piston stopper is made in one piece. In lines 3-10 of page 29, Pharma Gummi teach enclosing a piston section (37) of the piston stopper in a cap-shaped inert film (8) comprising a fluorinated polymer film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the base body of Pawlikowski substantially from an elastomer and in one piece as taught by Pharma Gummi as both Pawlikowski and Pharma Gummi disclose an elastomer such as rubber as being a suitable material for a piston stopper and Pharma Gummi teaches that it is well known to make the base body in one piece made substantially from an elastomer. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to provide the piston stopper of Pawlikowski with a receiving cavity as taught by Pharma Gummi as Pharma Gummi provides a receiving cavity on the piston stopper

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which can be used to connect to a displacement transferring element (similar to that shown in Figure 17 of Pharma Gummi). It would have been obvious to one having ordinary skill in the art at the time the invention was made to enclose the piston section of Pawlikowski in a cap-shaped inert film such as a fluorinated polymer film as taught by Pharma Gummi as Pharma Gummi teach that it is well known to provide an inert film on a piston section of a piston stopper which is facing the contents of a syringe cylinder to avoid unwanted interaction between the contents of the syringe cylinder and the rubber portion of the piston stopper (see line 16 of page 8 to line 10 of page 9).

6. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawlikowski in view of Pharma Gummi as applied to claim 15 above, and further in view of McConnaughey (U.S. Patent 2,895,773). Pawlikowski and Pharma Gummi disclose the piston stopper substantially as claimed. However, Pawlikowski and Pharma Gummi are silent to a section of an inside wall of the piston stopper bordering the receiving cavity having an internal thread to connect with a thread of the displacement transferring element. In Figure 3, McConnaughey show a section of an inside wall of the piston stopper with an internal thread (304b) to connect with a thread (322b) of a displacement transferring element (320) where the internal thread (304b) terminates at a spacing from a bottom (306) of the receiving cavity (310). The section with the internal thread (304b) terminates at the piston section (302a) or at a spacing from it and a cylindrical or tapered receiving cavity (at 321c in Figure 3a) extends between the internal thread (304b) and the section of the receiving cavity (310) which extends into the piston section (302a). As seen in Figure 3a, a cross-section of the

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receiving cavity (310) tapers out from the bottom (306) of the receiving cavity toward an opening of the receiving cavity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a section of an inside wall of the piston stopper bordering the receiving cavity of Pharma Gummi with an internal thread to connect with a thread of the displacement transferring element as taught by McConnaughey as McConnaughey teaches that it is well known to connect a piston stopper with a displacement transferring element using threads.

Response to Arguments

7. Applicant's arguments with respect to claims 15-20 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

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SUPERVISORY PATENT EXAMINER

